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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day-18-0891]

Agency Forms Undergoing Paperwork Reduction Act Review

In accordance with the Paperwork Reduction Act of 1995, the Centers for Disease Control and Prevention (CDC) has submitted the information collection request titled World Trade Center Health Program Enrollment, Treatment, Appeals & Reimbursement to the Office of Management and Budget (OMB) for review and approval. CDC previously published a "Proposed Data Collection Submitted for Public Comment and Recommendations" notice on May 11, 2018, to obtain comments from the public and affected agencies. CDC did not receive comments related to the previous notice. This notice serves to allow an additional 30 days for public and affected agency comments.

CDC will accept all comments for this proposed information collection project. The Office of Management and Budget is particularly interested in comments that:

- (a) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

- (b) Evaluate the accuracy of the agencies estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
- (c) Enhance the quality, utility, and clarity of the information to be collected;
- (d) Minimize the burden of the collection of information on those who are to respond, including, through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses; and
- (e) Assess information collection costs.

To request additional information on the proposed project or to obtain a copy of the information collection plan and instruments, call (404) 639-7570 or send an email to omb@cdc.gov. Direct written comments and/or suggestions regarding the items contained in this notice to the Attention: CDC Desk Officer, Office of Management and Budget, 725 17th Street, NW, Washington, DC 20503 or by fax to (202) 395-5806. Provide written comments within 30 days of notice publication.

Proposed Project

World Trade Center Health Program Enrollment, Treatment, Appeals & Reimbursement (OMB Control No. 0920-0891, Expires 09/30/2018)

– Revision – National Institute for Occupational Safety and Health (NIOSH), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

NIOSH seeks to request OMB approval to revise the currently approved information collection activities that support the World Trade Center (WTC) Health Program. The James Zadroga 9/11 Health and Compensation Act of 2010 (Pub. L. 111-347, as amended by Pub. L. 114-113) created the WTC Health Program to provide medical monitoring and treatment benefits to eligible individuals affected by the terrorist attacks on September 11, 2001. Eligible individuals include firefighters and related personnel, law enforcement officers, and rescue, recovery, and cleanup workers who responded to the attacks in New York City, at the Pentagon, and in Shanksville, Pennsylvania (responders), and to eligible persons who were present in the dust or dust cloud on September 11, 2001, or who worked, resided, or attended school, childcare, or adult daycare in the New York City disaster area (survivors).

This request also seeks to incorporate information collection previously approved under the World Trade Center Health Program Petition for the Addition of a New WTC-Related Health Condition for Coverage under the World Trade Center (WTC) Health Program (OMB No. 0920-0929, expiration date 7/31/2018),

which has been discontinued. The revision of OMB No. 0920-0891 will provide a comprehensive summary of information collection needed to administer the World Trade Center Health Program.

Since its inception in 2011, the WTC Health Program has been approved to collect information from applicants and Program members (enrolled WTC responders and survivors) concerning eligibility and enrollment, appointment of a designated representative, medical care, travel reimbursement, and appeal of adverse Program decisions. The WTC Health Program is also currently approved to collect information from Program medical providers, including health condition certification requests and pharmaceutical claims. The WTC Health Program has determined that some existing forms need to be updated, and new information collections related to a recent rulemaking should be added.

Changes to WTC Health Program regulations in 42 CFR part 88 will require the extension of existing information collections. Specifically, 42 CFR 88.13 establishes procedures for the appeal of Program decisions to disenroll Program members and deny enrollment to applicants. Appeals of enrollment denial decisions, which include the submission of appeal request letters, are currently approved; the Program proposes to extend this information collection to account for the burden of requests for appeal of disenrollment decisions. Of the over 70,000 Program members, we expect that 0.014 percent (10) will

be subsequently disenrolled from the Program. Of those, we expect that 30 percent (3) will appeal the disenrollment decisions. We estimate that the disenrollment appeal requests will take no more than 0.5 hours per respondent. The annual burden estimate is 2 hours (rounded).

Section 42 CFR 88.21 establishes procedures for the appeal of WTC Health Program decisions to decertify a WTC-related health condition, deny certification, and deny treatment authorization. Appeals of health condition certification denials and treatment authorization denials, which include the submission of appeal request letters, are currently approved; the Program proposes to extend this information collection to account for the burden of requests for appeal of decertification decisions. The information collection will also be expanded to allow Program members to provide additional information and/or an oral statement. Of the estimated 51,472 Program members who have at least one health condition certification, we estimate that 0.02 percent (10) will be decertified, and 50 percent (5) of those will appeal a decertification. We estimate that the appeal request letter will take no more than 0.5 hours per respondent. Providing additional information and/or an oral statement will take no more than one hour per respondent. The annual burden estimate for decertification appeals is 8 hours.

We further estimate that Program members request certification for 20,000 health conditions each year. Of those 20,000, we estimate that one percent (200) of certification requests are denied by the WTC Health Program. We also expect that 30 percent of denied certifications, or 60 individuals, will be appealed. We estimate that the appeals letter takes no more than 30 minutes and providing additional information and/or an oral statement will take no more than one hour. The burden estimate for certification denial appeals is 90 hours.

In addition, of the projected 51,472 Program members who receive medical care, we estimate that 0.05 percent (26) will appeal a determination by the WTC Health Program that the treatment being sought is not medically necessary. We estimate that the appeals letter will take no more than 30 minutes and providing additional information and/or an oral statement will take no more than one hour. The burden estimate for treatment authorization denial appeals is 39 hours.

Finally, 42 CFR 88.23 establishes procedures for the appeal of a WTC Health Program decision to deny reimbursement to a Program medical provider for treatment determined not to be medically necessary. Accordingly, the Program proposes the addition of information collected in the appeal request. We estimate that of the nearly 52,000 Program providers, we estimate that 1.15 percent (600) annually will be denied

reimbursement for treatment found to be not medically necessary or in accordance with treatment protocols, and will appeal the decision. We estimate that the appeal letter will take no more than 0.5 hours to compile. The burden estimate for treatment reimbursement denial appeals is 300 hours.

The revision request also includes the addition of a new form to allow applicants and Program members to grant permission to share information with a third person about an individual's application or case. We estimate that 30 applicants and members will submit a Health Insurance Portability and Accountability Act (HIPAA) Release Form annually. The form will take no longer than 0.25 hours to complete. The burden estimate for the HIPAA Release form is 8 hours.

The total estimated annualized burden hours are 14,063, an increase of 469 hours from the previously approved estimate of 13,594 hours. The revised estimate includes forms that have not been modified; changes due to the appeals processes authorized by 42 CFR 88.21 and 42 CFR 88.23; inclusion of the new HIPPA Release Form; incorporation of a form previously approved under OMB No. 0920-0929; and miscellaneous actions. The revision request provides a detailed summary of each change and its impact on the burden estimate.

Background and Brief Description

Type of Respondent	Form Name	No. of Respondents	No. Responses per Respondent	Average Burden per Response (in hours)
FDNY Responder	World Trade Center Health Program FDNY Responder Eligibility Application	45	1	30/60
General Responder	World Trade Center Health Program Responder Eligibility Application (Other than FDNY)	2,475	1	30/60
Pentagon/Shanksville Responder	World Trade Center Health Program Pentagon/Shanksville Responder	630	1	30/60
WTC Survivor	World Trade Center Health Program Survivor Eligibility Application (all languages)	1,350	1	30/60
General responder	Clinic Selection Postcard for new general responders in NY/NJ to select a clinic	2,475	1	15/60
Program Medical Provider	Physician Request for Certification (WTC-3)	20,000	1	30/60
Responder (FDNY and General Responder) / Survivor	Denial Letter and Appeal Notification - Enrollment	45	1	30/60
Responder	Disenrollment	3	1	30/60

(FDNY and General Responder) / Survivor	Letter and Appeal Notification - Enrollment			
Responder (FDNY and General Responder) / Survivor	Decertification Letter and Appeal Notification - Health Condition	5	1	1.5
Responder (FDNY and General Responder) / Survivor	Denial Letter and Appeal Notification - Health Condition Certification	60	1	1.5
Responder (FDNY and General Responder) / Survivor	Denial Letter and Appeal Notification - Treatment Authorization	26	1	1.5
Responder (FDNY and General Responder) / Survivor	WTC Health Program Medical Travel Refund Request	10	1	10/60
Program Members	Designated Representative Form	30	1	15/60
Program Member	HIPAA Release Form to allow the sharing of member information with a third party	30	1	15/60
Pharmacy	Outpatient prescription pharmaceuticals	150	261	1/60
Program Medical Provider	Reimbursement Denial Letter and Appeal Notification - Providers	600	1	30/60
Responder/Survivor/Advocate	Petition for the addition of health	60	1	1

(physician)	conditions			
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